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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,850	03/31/2005	Hank F. Kung	1694.0460002/JMC/BLS	5851

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.  
1100 NEW YORK AVENUE, N.W.  
WASHINGTON, DC 20005

EXAMINER
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STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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01/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/529,850

Applicant(s)

KUNG ET AL.

Examiner

Laura L. Stockton, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on March 31, 2005 {Prelim. Amendment}.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

Claims 1-36 are pending in the application.

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 6-9 and 34, drawn to compounds of Formula I wherein **X** is hydrogen or Sn(alkyl)<sub>3</sub> and **R**<sup>1</sup>, **R**<sup>2</sup> and **R**<sup>3</sup> do not represent a tetradentate metal ligand.

Group II, claim(s) 1-5 and 34, drawn to compounds of Formula I wherein **X** is <sup>125</sup>I, <sup>123</sup>I, <sup>131</sup>I, <sup>18</sup>F, <sup>76</sup>Br or <sup>77</sup>Br and **R**<sup>1</sup>, **R**<sup>2</sup> and **R**<sup>3</sup> do not represent a tetradentate metal ligand.

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Group III, claim 1 and 34, drawn to compounds of Formula I wherein **X** is hydrogen or  $\text{Sn}(\text{alkyl})_3$  and at least one of  $\text{R}^1$ ,  $\text{R}^2$  or  $\text{R}^3$  represents a tetradentate metal ligand.

Group IV, claim(s) 1, 5 and 34, drawn to compounds of Formula I wherein **X** is  $^{125}\text{I}$ ,  $^{123}\text{I}$ ,  $^{131}\text{I}$ ,  $^{18}\text{F}$ ,  $^{76}\text{Br}$  or  $^{77}\text{Br}$  and at least one of  $\text{R}^1$ ,  $\text{R}^2$  or  $\text{R}^3$  represents a tetradentate metal ligand.

Group V, claim(s) 10-14 and 34, drawn to compounds of Formula II wherein **X'** is  $\text{Sn}(\text{alkyl})_3$  and  $\text{R}^9$  and  $\text{R}^{10}$  do not represent a tetradentate metal ligand.

Group VI, claim(s) 10-15 and 34, drawn to compounds of Formula II wherein **X'** is  $^{125}\text{I}$ ,  $^{123}\text{I}$ ,  $^{131}\text{I}$ ,  $^{18}\text{F}$ ,  $^{76}\text{Br}$  or  $^{77}\text{Br}$  and  $\text{R}^9$  and  $\text{R}^{10}$  do not represent a tetradentate metal ligand.

Group VII, claim(s) 10-12 and 34, drawn to compounds of Formula II wherein **X'** is  $\text{Sn}(\text{alkyl})_3$  and at least one of  $\text{R}^9$  or  $\text{R}^{10}$  represents a tetradentate metal ligand.

Group VIII, claim(s) 10-12 and 34, drawn to compounds of Formula II wherein **X'** is  $^{125}\text{I}$ ,  $^{123}\text{I}$ ,  $^{131}\text{I}$ ,  $^{18}\text{F}$ ,  $^{76}\text{Br}$  or  $^{77}\text{Br}$  and at least one of  $\text{R}^9$  or  $\text{R}^{10}$  represents a tetradentate metal ligand.

Group IX, claim(s) 16-24, drawn to compounds of Formula III, which do not have a radioisotope complex.

Group X, claim(s) 16-28, drawn to compounds of Formula III, which have a radioisotope complex.

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Group XI, claim 29, drawn to compounds of Formula IV, which do not have a radioisotope complex.

Group XII, claim(s) 29 and 30, drawn to compounds of Formula IV, which have a radioisotope complex.

Group XIII, claims 31 and 34, drawn to compounds of Formula V wherein  $R^{30}$  and  $R^{31}$  do not represent  $^{125}\text{I}$ ,  $^{123}\text{I}$ ,  $^{131}\text{I}$ ,  $^{18}\text{F}$ ,  $^{76}\text{Br}$ ,  $^{77}\text{Br}$  or  $^{18}\text{Fluoro}(\text{C}_{1-5})\text{alkyl}$ .

Group XIV, claims 31 and 34, drawn to compounds of Formula V wherein at least one of  $R^{30}$  or  $R^{31}$  represents  $^{125}\text{I}$ ,  $^{123}\text{I}$ ,  $^{131}\text{I}$ ,  $^{18}\text{F}$ ,  $^{76}\text{Br}$ ,  $^{77}\text{Br}$  or  $^{18}\text{Fluoro}(\text{C}_{1-5})\text{alkyl}$ .

Group XV, claim 32, drawn to compounds of Formula VI, which do not have a radioisotope complex.

Group XVI, claim(s) 32 and 33, drawn to compounds of Formula VI, which have a radioisotope complex.

Group XVII, claim 35, drawn to a diagnostic composition comprising a radiolabeled compound of Formula I wherein  $X$  is hydrogen or  $\text{Sn}(\text{alkyl})_3$  and  $R^1$ ,  $R^2$  and  $R^3$  do not represent a tetradentate metal ligand.

Group XVIII, claim 35, drawn to a diagnostic composition comprising a radiolabeled compound of Formula I wherein  $X$  is  $^{125}\text{I}$ ,  $^{123}\text{I}$ ,  $^{131}\text{I}$ ,  $^{18}\text{F}$ ,  $^{76}\text{Br}$  or  $^{77}\text{Br}$  and  $R^1$ ,  $R^2$  and  $R^3$  do not represent a tetradentate metal ligand.

Group IXX, claim 35, drawn to a diagnostic composition comprising a radiolabeled compound of Formula I wherein  $X$  is hydrogen or  $\text{Sn}(\text{alkyl})_3$  and at least one of  $R^1$ ,  $R^2$  or  $R^3$  represents a tetradentate metal ligand.

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Group XX, claim 35, drawn to a diagnostic composition comprising a radiolabeled compound of Formula I wherein **X** is  $^{125}\text{I}$ ,  $^{123}\text{I}$ ,  $^{131}\text{I}$ ,  $^{18}\text{F}$ ,  $^{76}\text{Br}$  or  $^{77}\text{Br}$  and at least one of **R**<sup>1</sup>, **R**<sup>2</sup> or **R**<sup>3</sup> represents a tetradentate metal ligand.

Group XXI, claim 35, drawn to a diagnostic composition comprising a radiolabeled compound of Formula II wherein **X'** is  $\text{Sn(alkyl)}_3$  and **R**<sup>9</sup> and **R**<sup>10</sup> do not represent a tetradentate metal ligand.

Group XXII, claim 35, drawn to a diagnostic composition comprising a radiolabeled compound of Formula II wherein **X'** is  $^{125}\text{I}$ ,  $^{123}\text{I}$ ,  $^{131}\text{I}$ ,  $^{18}\text{F}$ ,  $^{76}\text{Br}$  or  $^{77}\text{Br}$  and **R**<sup>9</sup> and **R**<sup>10</sup> do not represent a tetradentate metal ligand.

Group XXIII, claim 35, drawn to a diagnostic composition comprising a radiolabeled compound of Formula II wherein **X'** is  $\text{Sn(alkyl)}_3$  and at least one of **R**<sup>9</sup> or **R**<sup>10</sup> represents a tetradentate metal ligand.

Group XXIV, claim 35, drawn to a diagnostic composition comprising a radiolabeled compound of Formula II wherein **X'** is  $^{125}\text{I}$ ,  $^{123}\text{I}$ ,  $^{131}\text{I}$ ,  $^{18}\text{F}$ ,  $^{76}\text{Br}$  or  $^{77}\text{Br}$  and at least one of **R**<sup>9</sup> or **R**<sup>10</sup> represents a tetradentate metal ligand.

Group XXV, claim 35, drawn to a diagnostic composition comprising a radiolabeled compound of Formula V wherein **R**<sup>30</sup> and **R**<sup>31</sup> do not represent  $^{125}\text{I}$ ,  $^{123}\text{I}$ ,  $^{131}\text{I}$ ,  $^{18}\text{F}$ ,  $^{76}\text{Br}$ ,  $^{77}\text{Br}$  or  $^{18}\text{Fluoro(C}_{1-5}\text{)alkyl}$ .

Group XXVI, claim 35, drawn to a diagnostic composition comprising a radiolabeled compound of Formula V wherein

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at least one of  $R^{30}$  or  $R^{31}$  represents  $^{125}\text{I}$ ,  $^{123}\text{I}$ ,  $^{131}\text{I}$ ,  $^{18}\text{F}$ ,  $^{76}\text{Br}$ ,  $^{77}\text{Br}$  or  $^{18}\text{Fluoro}(\text{C}_{1-5})\text{alkyl}$ .

Group XXVII, claim 36, drawn to a method of imaging amyloid deposits comprising using a diagnostic composition comprising a compound of Formula I wherein  $X$  is hydrogen or  $\text{Sn}(\text{alkyl})_3$  and  $R^1$ ,  $R^2$  and  $R^3$  do not represent a tetradentate metal ligand.

Group XXVIII, claim 36, drawn to a method of imaging amyloid deposits comprising using a diagnostic composition comprising a compound of Formula I wherein  $X$  is  $^{125}\text{I}$ ,  $^{123}\text{I}$ ,  $^{131}\text{I}$ ,  $^{18}\text{F}$ ,  $^{76}\text{Br}$  or  $^{77}\text{Br}$  and  $R^1$ ,  $R^2$  and  $R^3$  do not represent a tetradentate metal ligand.

Group IXXX, claim 36, drawn to a method of imaging amyloid deposits comprising using a diagnostic composition comprising a compound of Formula I wherein  $X$  is hydrogen or  $\text{Sn}(\text{alkyl})_3$  and at least one of  $R^1$ ,  $R^2$  or  $R^3$  represents a tetradentate metal ligand.

Group XXX, claim 36, drawn to a method of imaging amyloid deposits comprising using a diagnostic composition comprising a compound of Formula I wherein  $X$  is  $^{125}\text{I}$ ,  $^{123}\text{I}$ ,  $^{131}\text{I}$ ,  $^{18}\text{F}$ ,  $^{76}\text{Br}$  or  $^{77}\text{Br}$  and at least one of  $R^1$ ,  $R^2$  or  $R^3$  represents a tetradentate metal ligand.

Group XXXI, claim 36, drawn to a method of imaging amyloid deposits comprising using a diagnostic composition comprising a compound of Formula II wherein  $X'$  is  $\text{Sn}(\text{alkyl})_3$  and  $R^9$  and  $R^{10}$  do not represent a tetradentate metal ligand.

Group XXXII, claim 36, drawn to a method of imaging amyloid deposits comprising using a diagnostic composition comprising a compound of Formula II wherein

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**X'** is  $^{125}\text{I}$ ,  $^{123}\text{I}$ ,  $^{131}\text{I}$ ,  $^{18}\text{F}$ ,  $^{76}\text{Br}$  or  $^{77}\text{Br}$  and **R**<sup>9</sup> and **R**<sup>10</sup> do not represent a tetradentate metal ligand.

Group XXXIII, claim 36, drawn to a method of imaging amyloid deposits comprising using a diagnostic composition comprising a compound of Formula II wherein **X'** is  $\text{Sn}(\text{alkyl})_3$  and at least one of **R**<sup>9</sup> or **R**<sup>10</sup> represents a tetradentate metal ligand.

Group XXXIV, claim 36, drawn to a method of imaging amyloid deposits comprising using a diagnostic composition comprising a compound of Formula II wherein **X'** is  $^{125}\text{I}$ ,  $^{123}\text{I}$ ,  $^{131}\text{I}$ ,  $^{18}\text{F}$ ,  $^{76}\text{Br}$  or  $^{77}\text{Br}$  and at least one of **R**<sup>9</sup> or **R**<sup>10</sup> represents a tetradentate metal ligand.

Group XXXV, claim 36, drawn to a method of imaging amyloid deposits comprising using a diagnostic composition comprising a compound of Formula V wherein **R**<sup>30</sup> and **R**<sup>31</sup> do not represent  $^{125}\text{I}$ ,  $^{123}\text{I}$ ,  $^{131}\text{I}$ ,  $^{18}\text{F}$ ,  $^{76}\text{Br}$ ,  $^{77}\text{Br}$  or  $^{18}\text{Fluoro}(\text{C}_{1-5})\text{alkyl}$ .

Group XXXVI, claim 36, drawn to a method of imaging amyloid deposits comprising using a diagnostic composition comprising a compound of Formula V wherein at least one of **R**<sup>30</sup> or **R**<sup>31</sup> represents  $^{125}\text{I}$ ,  $^{123}\text{I}$ ,  $^{131}\text{I}$ ,  $^{18}\text{F}$ ,  $^{76}\text{Br}$ ,  $^{77}\text{Br}$  or  $^{18}\text{Fluoro}(\text{C}_{1-5})\text{alkyl}$ .

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.



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The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain a phenyl ring which does not define a contribution over the prior art. See, for example, CA Registry Number 71-43-2 in CA 0:412, 1906. The substituents on the phenyl vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;

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- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144.

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If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

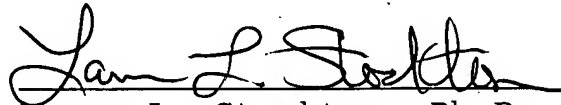
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

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Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", with a stylized flourish at the end.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600.

January 7, 2008